Zoster Vaccine

Criteria for Use

May 2013

VA Pharmacy Benefits Management Services, Medical Advisory Panel, and VISN Pharmacist Executives

The following recommendations are based on medical evidence, clinician input, and expert opinion. The content of the document is dynamic and will be revised as new information becomes available. The purpose of this document is to assist practitioners in clinical decision-making, to standardize and improve the quality of patient care, and to promote cost-effective drug prescribing. The clinician should utilize this guidance and interpret it in the clinical context of the individual patient. Individual cases that are outside the recommendations should be adjudicated at the local facility according to the policy and procedures of its P&T Committee and Pharmacy Services. The Product Information should be consulted for detailed prescribing information.

Exclusion Criteria *If the answer to ANY item below is met, then the patient should NOT receive vaccine.*

☐ History of anaphylactic /anaphylactoid reaction to gelatin, neomycin, or any other component of the vaccine

☐ History of primary or acquired immunodeficiency states including leukemia that is not in remission or that has been treated with chemotherapy or radiation within the previous 3 months; lymphomas of any type, or other malignant neoplasms affecting the bone marrow or lymphatic system; AIDS, other clinical manifestations of human immunodeficiency virus (HIV), and CD4+ count of ≤ 200 cells/µl or ≤ 15% total lymphocytes; or other unspecified cellular immunodeficiency based on clinical or laboratory evidence. For CD4+ count > 200 cells/µl, hematopoietic stem cell transplantation (HSCT), AND recombinant human immune mediators and modulators see *Consider Benefits Versus Risks.*

☐ Receiving immunosuppressive therapy, including high-dose corticosteroids (≥ 20 mg/d of prednisone or equivalent) lasting 2 or more weeks. This includes patients who have received organ transplants. (see under Dosing, Administration, and Storage).

☐ Active untreated tuberculosis

☐ Pregnant or may be pregnant

☐ Moderate or severe acute illnesses with or without fever (vaccination should be deferred until after the patient improves)

☐ Receiving antiviral therapy that inhibits varicella zoster virus replication (e.g., acyclovir, valacyclovir, famciclovir, ganciclovir, foscarnet, cidofovir, etc.), unless these medications can be temporarily discontinued (see under Dosing, Administration, and Storage).

☐ Intended use is to treat acute HZ or to prevent postherpetic neuralgia in persons with acute HZ

Inclusion Criteria *The answers to one of the following must be fulfilled in order to meet criteria.*

☐ Age 60 years and older and immunocompetent at the time of vaccination, regardless of whether the patient reports a prior episode of chickenpox or herpes zoster (HZ). This includes persons

- with chronic medical conditions, unless those conditions are contraindications or precautions;
- with a prior physician-diagnosed HZ rash (these persons can frequently have recurrences even shortly after the initial episode)[1];
- with leukemia in remission and not treated with chemotherapy (e.g., alkylating drugs or antimetabolites) or radiation for at least 3 months;
- receiving low- to moderate-dose (less than 20 mg/d of prednisone or equivalent) or short-term corticosteroid therapy (less than 14 days); intranasal, dermal, inhaled corticosteroids; intra-articular, bursal, or tendon injections of corticosteroids; or long-term alternative-day treatment with low to moderate doses of short-acting systemic corticosteroids;
- receiving low-dose methotrexate (0.4 mg/kg/wk or less), azathioprine (3 mg/kg/d or less), or 6-mercaptopurine (1.5 mg/kg/d or less) for treatment of rheumatoid arthritis, psoriasis, polymyositis, sarcoidosis, inflammatory bowel disease, and other conditions;
- with impaired humoral immunity (e.g., hypogammaglobulinemia or dysgammaglobulinemia)

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Updated versions may be found at http://www.pbm.va.gov or http://vaww.pbm.va.gov

Consider Benefits Versus Risks

☐ AIDS / HIV infection with CD4+ count > 200 cells/µl. Zoster vaccine is specifically *contraindicated* if the CD4+ count is 200 cells/µl or less or total lymphocytes is 15% or less. There is no data on the use of zoster vaccine in HIV-infected individuals with CD4+ counts greater than 200 cells/uL.

☐ Hematopoietic stem cell transplantation (HSCT). Experience is limited. Assess patient's immune status and risk–benefits on a case-by-case basis. If vaccination is decided upon, administer zoster vaccine at least 24 months after transplantation.

☐ Receiving recombinant human immune mediators and immune modulators, especially the antitumor necrosis factor agents such as adalimumab, etanercept, and infliximab. The safety and efficacy of concurrent administration of these agents with zoster vaccine are unknown. If it is not possible to administer zoster vaccine before initiation of therapy, assess the patient's immune status and risk–benefits on a case-by-case basis. Otherwise, wait at least 1 month after discontinuing the immune mediator / modulator therapy before administering zoster vaccine.

Dosage, Administration and Storage

One dose (0.65 ml) by subcutaneous injection. *A booster dose is not FDA-approved.*

Timing of administration in special situations:

- *Persons anticipating immunosuppression.* Administer zoster vaccine at the first possible visit while immunity is still intact and at least 14–30 days before beginning immunosuppressive therapy, if delay is possible.
- *Persons receiving antiviral therapy that inhibits varicella zoster virus replication (e.g., acyclovir, valacyclovir, famciclovir, ganciclovir, foscarnet, cidofovir, etc*. Temporarily discontinue these medications from at least 24 hours before administering zoster vaccine to at least 14 days after, if possible.
- *Persons who recently discontinued high-dose corticosteroids.* Defer zoster vaccination for at least 1 month after discontinuation of high-dose corticosteroids (20 mg/d or greater of prednisone or equivalent for 2 or more weeks).
- *Persons undergoing hematopoietic stem cell transplantation.* If, after a case-by-case risk–benefit assessment, it is decided to administer zoster vaccine, defer zoster vaccination for at least 24 months after transplantation.
- *Persons receiving recombinant human immune mediators and immune modulators, especially the antitumor necrosis factor agents such as adalimumab, infliximab, and etanercept.* If, after a case-by-case risk–benefit assessment, it is decided to administer zoster vaccine, defer vaccination for at least 1 month after discontinuation of the immune mediator/modulator therapy

Zoster vaccine must be protected from light. It SHOULD BE STORED FROZEN at an average temperature of -15°C (+5°F) or colder until it is reconstituted for injection. Any freezer, including frost-free, that has a separate sealed freezer door and reliably maintains an average temperature of -15°C or colder is acceptable for storing zoster vaccine. Zoster vaccine may be stored and/or transported at refrigerator temperature (2° to 8°C, 36° to 46°F) for up to 72 continuous hours prior to reconstitution. Vaccine stored at 2° to 8°C (36° to 46°F) that is not used within 72 hours of removal from –15°C (+5°F) storage should be discarded. The diluent should be stored separately at room temperature (20 to 25°C, 68 to 77°F), or in the refrigerator. THE VACCINE SHOULD BE ADMINISTERED IMMEDIATELY AFTER RECONSTITUTION TO MINIMIZE LOSS OF POTENCY. DISCARD RECONSTITUTED VACCINE IF IT IS NOT USED WITHIN 30 MINUTES. DO NOT FREEZE reconstituted vaccine.

Issues for Consideration

FDA Indication and ACIP Recommendations

- In May 2006, FDA approved zoster vaccine for prevention of herpes zoster in adults aged 60 years and older. In March 2011, FDA extended indication to adults 50-59 years old.
- CDC's ACIP Adult Immunization Schedule states that a single dose of zoster vaccine is recommended for adults aged 60 years and older regardless of whether they report a previous episode of herpes zoster. In June 2011, ACIP maintained existing recommendation for zoster vaccination in adults aged 60 years and older (i.e, . ACIP did not recommend expansion of zoster vaccine to cover persons aged 50 – 59 years old). The ACIP Zoster Vaccine Working Group cited two reasons for maintaining vaccination aged 60 years and old: 1) Insufficient evidence regarding duration of vaccine protection to vaccinate well before peak of zoster incidence 2) inappropriate to expand recommendations while zoster remains in short supply.
- Before routine administration of zoster vaccine, it is not necessary to ask patients about their history of varicella (chickenpox) or to conduct serologic testing for varicella immunity. However, if there is existing evidence of non-immunity to chickenpox (e.g., negative antibody titers), then offer chickenpox vaccine instead.

Simultaneous Administration with Other Vaccines for Adults Aged 60 years and older

- The FDA-approved product information for zoster vaccine states that zoster vaccine and pneumococcal polysaccharide polyvalent vaccine should not be given concurrently because concomitant use reduces the immunogenicity of zoster vaccine; co-administration did not affect the immunogenicity of the pneumococcal vaccine. However, since the clinical relevance of this observation is not known, the CDC states that zoster vaccine and pneumococcal polysaccharide polyvalent vaccine can be co-administered to prevent missed opportunities for zoster vaccination. The VA PBM, NCP, and Public Health recommend that the zoster vaccine and pneumococcal polysaccharide polyvalent vaccine should be administered 4 weeks apart if feasible but may be concomitantly administered to avoid a missed opportunity to provide both vaccines.
- Live, attenuated vaccines: No data available. CDC recommends if simultaneous administration is not possible, zoster vaccine should be administered at least 4 weeks before or after another live, attenuated vaccine.
- Trivalent inactivated influenza vaccine. Immunogenicity is not compromised; may administer simultaneously.
- Other inactivated vaccines *(e.g., Td, Tdap):* No data available; according to CDC recommendations, zoster vaccine can be given on the same day, any time before or after an inactivated vaccine.
- If zoster vaccine is administered simultaneously with another vaccine, each vaccine must be administered in separate syringes at different body sites.

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1. Varicella Virus Vaccine Live (Oka / Merck)
2. Shingles Prevention Study (Oxman MN, et al. N Engl J Med 2005;352:2271-84): http://content.nejm.org/cgi/reprint/352/22/2271.pdf
3. Prevention of Herpes Zoster. MMWR 2008. June 6; 57 (RR-5):1–30. Available at: http://www.cdc.gov/mmwr/PDF/rr/rr5705.pdf Accessed 08 June 2008.
4. ACIP Recommended Adult Immunization Schedule — United States, 2013 available at: http://www.cdc.gov/vaccines/schedules/index.html
5. MMWR General Recommendations on Immunization on Immunization Practices (ACIP). January 28, 2011. Volume 60/No 2.
6. MMWR on Herpes Zoster Vaccine: Licensure for Persons Aged 50 through 59 Years. November 11, 2011. Volume 60/No 44. http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6044a5.htm?s_cid=mm6044a5_e%0d%0a
7. ACIP June 2011 Meeting Slides http://www.cdc.gov/vaccines/acip/meetings/meetings-info.html